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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,137	09/25/2006	Mats Inganas	HO-P02773US1	1324

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
09/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,137	INGANAS ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-29* is/are pending in the application.

4a) Of the above claim(s) *3-6,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-17,19-21 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 1 is acknowledged and has been entered.

2. Claims 1, 2, 7-17, 19-21, 24-29

3. Claims 3-6, 22, 23 are withdrawn.

Claim Objections

4. Claim 7 is objected to because of the following informalities: the claim fails to indicate which claim it depends from. Appropriate correction is required. For purposes of examination, it is assumed that the dependency has not changed from the previous set of claims, and that claim 7 remains dependent from claim 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, 8-17, 19-21, 25-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. [US 2003/0053934] in view of Yager et al. [US 2003/0124623].

With respect to claims 1, 2, Andersson et al. teach a microfluidic device with microchannel structures comprising a porous matrix placed in a microcavity or immediately downstream a microcavity, a packed bed of monosized particles in the microcavity (para. 0016),

wherein the microcavity may further comprise a solid phase with an immobilized affinity reactant (para. 0017). Andersson et al. further teach that these affinity reactants may comprise proteins and antibodies, nucleic acids, lectins and carbohydrates (para. 0087). Andersson et al. fails to teach that the microcavities comprise a bed-preserving agent comprising a compound exhibiting a hydrophilic group and is water-soluble.

Yager et al., however, teach a microfluidic device comprising a microfluidic channel and storage area on a wall of the microfluidic channel with a solid reagent plug comprising a matrix, and a reagent comprising particulate materials such as microspheres or nanoparticles having an affinity for binding to the analyte (para. 0011-0017, 0087). Yager et al. further teach that the matrix comprises preservatives such as trehalose and dextran (para. 0089), which are water soluble and exhibit hydrophilic groups. Yager et al. further teach that the once the reagent solutions are rendered solid and dry, the reagents are very robust with respect to storage, wherein the reagents may comprise proteins, antibodies, and nucleic acid probes (para. 0087, 0103-0104, 0109).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the matrix of microparticles comprising reagents with the bed-preserving agent of Yager et al. into the device of Andersson et al. in order to be able to render the reactants in the device of Andersson in a solid and dry state, such that the device may be stored in conjunction with reagents in a robust manner, thus obviating the need for keeping the reagents separate from the device during storage of the device. Alternatively, it would have been obvious to combine the storage and reaction areas of Yager et al., as presented by Andersson et

al., so that the reagents would not need to travel as far, thus eliminating the potential of reagent loss.

7. With respect to claim 8, 9, Yager et al. teach that the microfluidic device may be in a dry state (para. 0104). It is noted that claims 8 and 9 recite product by process limitations. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

8. With respect to claims 10-11, Andersson et al. teach a microfluidic device comprising a porous matrix placed in a microcavity or immediately downstream a microcavity, a packed bed of monosized particles in the microcavity (para. 0016), wherein the particles would be either swellable or non-swellable.

9. With respect to claims 12, 13, Andersson et al. teach an inlet microconduit connected to an inlet port via a volume defining unit that comprises a metering microcavity with valves associated with the outlet ports (para. 0065), wherein the inlet microconduits may simultaneously distribute liquid aliquots to several separate microchannel structures (para. 0066).

10. With respect to claim 14, Andersson et al. teaches that a microfluidic device comprising a metering system capable of delivering fluid and passive valves for controlling fluid flow (para. 0065-0068). Therefore, the metering system of Andersson et al. would have sufficient hydrophilicity for being filled by capillarity once an aqueous liquid enters the unit.

11. With respect to claim 15, fluid is delivered by centrifugal force (para. 0064).

12. With respect to claims 16, 17, 19-21, Andersson et al. teach that the immobilization of the reactant may comprise streptavidin and a biotinylated affinity reactant (para. 0090), wherein streptavidin would constitute the recited ligand L, and the biotinylated affinity reactant would constitute B-AC_s. Since the binding is between streptavidin and biotin, the affinity constant would not be more than 10^3 larger than the affinity constant for streptavidin and biotin.

13. With respect to claims 25-27 Andersson et al. teach that the immobilization of the reactant may comprise streptavidin and a biotinylated affinity reactant (para. 0090).

14. With respect to claim 29, the antibodies of Yager et al. would have an affinity constant for formation of the complex between the antibody and a desired solute such as an analyte. Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, one of ordinary skill in the art would have found it obvious for the affinity constant for the formation of the complex to be no more than 10^{-6} mole/L, through normal optimization procedures known in the art.

15. Claims 7, 24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. [US 2003/0053934] in view of Yager et al. [US 2003/0124623], as applied to claim 1 above, and further in view of Glezer et al. [US 2004/0189311].

With respect to claims 7, 24, 28, Andersson et al. and Yager et al. teach a matrix comprising reagents such as a preservation agent such as trehalose or dextran, but do not teach buffers such as phosphate buffers with a potassium counter-ion.

Glezer et al., however, teach dry reagent that may include a neutralizing reagent such as phosphate buffering agents (para. 0201), and further teach that this allows for the pH of the extracted sample to be brought to a value that is compatible with subsequent assay reactions carried out on the sample.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the reagent of Andersson et al. and Yager et al. to comprise phosphate buffering agents, as suggested by Glezer et al., in order that the extracted samples may be better prepared for subsequent assay reactions and analysis, and the use of a potassium buffer in the device of Andersson et al. would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 8, 16-17, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/550,182. In particular, the conflicting application recites two or more different sets of microchannel structures comprising a reaction microcavity in which there is a solid phase with an immobilized affinity ligand L directed toward a binder B (claim 1) and wherein the solid phase is in a dry state comprising one or more bed-preserving agents (claim 13). Although the conflicting application does not recite that the reaction microcavity is intended for retaining a solid phase material in the form of a wet porous bed, it would be capable of doing so, and therefore, would render the conflicting application obvious over the instant claims.

18. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

19. Applicant's arguments filed July 20, 2010 have been fully considered but they are not persuasive.

20. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, with respect to applicant's argument that Andersson et al. fail to teach

a preservative or that the reagents are even in a solid and dry state, so there would not be any need for a preservative, the Office notes that the two are in fact linked. More specifically, Yager et al. discloses the presence of preservatives such as trehalose and dextran replace the waters of hydration surrounding a reagent thus would render the reagents in a solid and dry state. Yager further provides motivation for doing so, disclosing that this would preserve the function and/or viability of the reagent during storage (para. 0088-0091).

21. In response to applicant's argument on p. 7 that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the present invention need not support any immobilized reagent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

22. With respect to applicant's arguments on p. 7-8 that Andersson does not specify a need to preserve the reagents, the Office notes that if Andersson had disclosed a need for a preservative, the rejection would most likely have been an anticipatory rejection under 35 USC 102, and not an obviousness rejection, as Anderson et al. would have disclosed all the limitations of claim 1. The Office notes that with respect to applicant's assertion that "there was no reason identified that would have led the skilled artisan to make the modification", the Office notes the reason may be found in either reference. In fact, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior

case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). In this situation, the motivation and reasonable expectation for success for adding a preservative to a reagent is provided by Yager et al., who discloses that the presence of preservatives such as trehalose and dextran replace the waters of hydration surrounding a reagent and preserve the function and/or viability of the reagent during storage, thus providing the advantage of allowing reagents to be stored with the microfluidic device while preserving the function and/or viability of the reagents during storage, which is not discussed by Andersson et al. More specifically, Yager et al. states that “once reagent solutions are rendered solid by any acceptable method, the reagents are very robust with respect to storage", indicating that when not solid, the reagents are not robust with respect to storage. Furthermore, the Office notes that the reagents preserved by Yager et al. are the same as the reagents of Andersson et al., and therefore there would have been a reasonable expectation of success in preserving the reagents of Andersson et al. Therefore, contrary to applicant’s assertions, a reason for the modification has in fact been discussed, to render the microfluidic device suitable for storage, as well as a reasonable expectation of success. In fact, the only difference between Yager et al. and the

claims is that the storage area and the reaction area in the claims are the same (the microcavity), which is taught by Andersson et al.

23. In response to applicant's amendment of claim 1 to recite "one or more compounds capable of stabilizing the solid phase material during transformation of a wet state of the solid phase material to the dry state.... and assisting in restoring the dry state solid phase material to a wet porous bed", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). More specifically, it appears from the specification that these are all performed by compounds such as trehalose (see p. 6, lines 20-33, p. 10, lines 5-11), and therefore the claims would still remain obvious over the prior art.

24. Applicant's arguments with respect to claims 7, 24, and 28, appear to rely on their arguments regarding claim 1, which have been addressed above.

25. With respect to applicant's arguments regarding the double patenting rejections, the arguments are acknowledged.

Conclusion

26. No claims are allowed.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Primary Examiner, Art Unit 1641